K131016

510(k) Summary
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25-Nov-13

NOV 27 2013

MOLECULAR PRODUCTS LTD
Parkway, Harlow Business Park
Harlow, UNITED KINGDOM CM19 5FR

Tel – 011 44 1279 401200
Fax - 011 44 1279 401231

Official Contact: Dr. Mandy Humphreys, Technical Director

Proprietary or Trade Name: ROGS

Common/Usual Name: Portable oxygen generator

Classification Name: Portable Oxygen Generator
CAW – 868.5440
Class 2

Predicate Devices: Molecular Products - POGS – K062153

Device Description
The ROGS is a chemical based portable oxygen generator which generates 99% oxygen for at least 15 minutes at a flow rate of at least 6 lpm. It is a self-contained device with the oxygen delivered via standard oxygen face mask or nasal cannula.

Indications for Use
Intended to produce oxygen for emergency use at 6 lpm flow rate for at least 15 minutes (90 liters).

Environment of Use
Emergency – OTC – home and emergency settings

Performance Testing
Performance testing was performed:

- VOC / $PM_{2.5}$ / Ozone
- Environmental testing – high and low temperature conditions
- Mechanical testing – vibration
- Flow rate and flow duration
- External container temperature
- Outlet gas temperature
- % oxygen generated

The proposed device met and passed all the performance testing as outlined above.

Comparative Table – OTC – Emergency Use

Features	Predicate Molecular Products POGS K062153	Proposed Device ROGS OTC - Emergency Use
Indications for use	To produce oxygen for emergency use	To produce oxygen for emergency use
Environment of Use	Home, emergency locations	Home, emergency locations
Patient Population	Any individual	Any individual
Contraindications	None	None
Method for oxygen generation	Chemical reaction	Chemical reaction
Patient interface	Standard oxygen mask or nasal cannula	Standard oxygen mask or nasal cannula
Specifications	% Oxygen – 99% Flow rate minimum – 6 lpm Duration at least15 minutes Initiation of oxygen flow – 60 secs	% Oxygen – 99% Flow rate minimum – 6 lpm Duration at least15 minutes Initiation of oxygen flow – 5 secs
Single use, disposable	Yes	Yes
OTC designation	Yes	Yes
Flow rate	> 6 lpm	> 6 lpm
Duration of flow	At least 15 minutes	At least 15 minutes
% oxygen purity	>99%	> 99%
VOC / $PM_{2.5}$ testing	Yes	Yes
Housing temperature	<45°C Maximum	<45°C Maximum
Temperature of gas at outlet	<40°C Maximum	<40°C Maximum
Time to start of gas flow	60 seconds	5 seconds
Storage temperatures	-20° to + 40 °C / -4° to +104°F	-20° to + 40 °C / -4° to +104°F
Operating Temperatures	0° to + 40 °C / 32° to +104°F	0° to + 40 °C / 32° to +104°F
Dimensions	35 cm x 10 cm	28.5 cm x 11.5 cm
Gross weight	1.8 kg	1.5 kg
Accessories	Mask or Oxygen cannula	Mask or Oxygen cannula

OTC - Emergency Use Substantial Equivalence

The ROGS for Emergency Use - OTC is viewed as substantially equivalent to the predicate device because:

Indications for Use –
The ROGS for Emergency Use - OTC has the identical indications for use as the predicate – K062153, namely for emergency use which permits it to be labeled OTC.
Discussion – The indications for use are identical to the predicate – K062153.

Technology –
The ROGS for Emergency Use - OTC utilizes solid chemicals which are ignited when the starter is activated. There is a chemical reaction which generates oxygen. The chemical used in the chemical reaction to generate oxygen are identical technology to predicate – K062153.
Discussion – The technology and mode of operation is identical to the predicate – K062153.

Materials –
The materials in the gas pathway have been tested via VOC and $PM_{2.5}$ as is expected for such devices. The test results demonstrate that the ROGS for Emergency Use - OTC does not generate unwanted particulate matter or undesirable gases. This is similar to the predicate – K062153.
Discussion – The materials are identical to the predicate – K062153.

Environment of Use –
The ROGS for Emergency Use - OTC has the identical environments of use, i.e. home and emergency settings, as does the predicate – K062153.
Discussion – The environment of Use is identical to the predicate – K062153.

Patient Population –
The patient population is specified as "any individual" by the predicate in the 510(k) Summary but the intended use is for individuals requiring oxygen in an emergency setting.
Discussion – The patient population is identical to the predicate – K062153.

Non-clinical Performance Testing –
The ROGS for Emergency Use - OTC has the minimum performance specifications required to meet emergency use, which are – at least a flow rate of 6 lpm for at least 15 minutes. This is identical to the predicate – K062153.

We performed the following bench tests:

- VOC / $PM_{2.5}$ / Ozone
- Environmental testing – high and low temperature conditions
- Mechanical testing – vibration
- Flow rate and flow duration
- External container temperature
- Outlet gas temperature
- % oxygen generated

Substantial Equivalence Conclusion –

The Molecular Products ROGS for Emergency Use – OTC is equivalent to the predicate, K062153, based upon performance specifications and testing and the FDA *Guidance* requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 27, 2013

Molecular Products, Limited
C/O Mr. Paul Dryden
Consultant
24301 Woodsage Dr.
Bonita Springs, FL 34134

Re: K131016
Trade/Device Name: ROGS
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: October 29, 2013
Received: October 30, 2013

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131016

Device Name
ROGS portable oxygen generator – Emergency - OTC

Indications for Use *(Describe)*
Intended to produce oxygen for emergency use at 6 lpm flow rate for at least 15 minutes (90 liters).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Chan O. Lee -S
Date: 2013.11.27 11:19:46 -05'00'